Enforcement Updates and Compliance Risks Associated with the Opioid Crisis.

Natalie A. Waites
Assistant Director
Fraud Section, Civil Division
Department of Justice

Robert G. Trusiak, Esq.
www.trusiaklaw.com

HEALTH CARE COMPLIANCE ASSOCIATION
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Opioid Multidistrict Litigation: Important Takeaways and Case Horizon

Natalie A. Waites
Assistant Director
Fraud Section, Civil Division
Department of Justice

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Overview

- MDL Background
- Settlement
- Significant Decisions
- Case Horizon

MDL Background

- **Formed in December 2017; Assigned to Judge Dan Polster in the N.D. Ohio**
- **Who is Involved?**
  - Plaintiffs: 2,000+ cases, primarily cities and counties, but also tribes, insurers, babies
  - Defendants: ~500 defendants, primarily opioid manufacturers, distributors, and pharmacies, but also includes some individuals
- **What is Alleged?**
  - Plaintiffs allege that the manufacturers of prescription opioids grossly misrepresented the risks of long-term use of those drugs for persons with chronic pain, and distributors failed to properly monitor suspicious orders of those prescription drugs.
  - Federal and state RICO, consumer protection, and state controlled-substance law claims, as well as common law claims such as public nuisance, negligence, negligent misrepresentation, fraud, and unjust enrichment.

MDL Background

- **Bellwether Model for discovery and limited trials in N.D. Ohio**
  - Track 1A - pharmaceutical manufacturers and distributors
  - Track 1B – pharmacies – distribution claims
  - Track 3 – pharmacies – dispensing claims
- **Remanded Cases**

Settlement

Settlement

- Court has been vocal about ultimate need for a global resolution to provide a “meaningful solutions to a national crisis”

- Special Master devoted to settlement

Settlement

- Plaintiffs proposed and Court approved a novel "negotiating class" pursuant to FRCP 23. *In re: National Prescription Opiate Litig.*, 332 F.R.D. 532 (N.D. Ohio 2019)
  - Class certification and opt-out process occur *prior to* a settlement being reached

- 6th Circuit reversed certification, concluding that negotiation class could not be squared with FRCP 23. *In re: National Prescription Opiate Litig.*, _ F.3d _, 2020 WL 5701916 (6th Cir. Sept. 24, 2020)

Significant Decisions

Track 1A Summary Judgment

- The Court granted Plaintiffs' Motion for Summary Judgment on whether the Controlled Substances Act imposes certain duties on registrants.
  - Found an "identification duty" to operate a system to detect suspicious orders;
  - a "reporting duty" to report suspicious orders to the DEA; and
  - a "no-shipping" duty to decline to ship a suspicious order "until the registrant can determine, through investigation, that the order is not likely to be diverted."

Track 1A Summary Judgment

(Cont.)

- Expressly adopted the Special Master's Discovery Ruling No. 12 [Dkt. 1174], which stated "it is clear that distributors are required to identify suspicious orders from pharmacies and cannot ship those orders unless investigation shows them to be legitimate."

- The Court denied Plaintiffs' MSJ as to whether the Defendants violated these duties as a matter of law, concluding that there were materials facts in dispute.

In re National Prescription Opiate Litig., 2019 WL 3917575 (N.D. Ohio Aug. 19, 2019)

Track 3: Motion to Dismiss

- Pharmacy Defendants argued that only their pharmacist-employees – and not the Defendants themselves – have a duty under the Controlled Substances Act to prevent diversion of opioids via illegitimate prescriptions. The Court disagreed:
- Interpreted 21 CFR § 1306.04(a) subjects the pharmacy, as well as the pharmacy, to penalties for violating the CSA
- Rejected argument that there is no corporate-level obligation to design and implement systems, policies, or procedures to identify red flag prescriptions

In re National Prescription Opiate Litig., _ F. Supp.3d _, 2020 WL 4550400 (N.D. Ohio Aug. 6, 2020)

Track 3: Motion to Dismiss

- Subsequently denied Motion for Reconsideration or Certification, but noted:
- "The Court agrees with Defendants that portions of its Opinion can be read as imputing specific requirements in the CSA that are not present in the text of the Act…. Therefore the Court not clarifies the CSA and its regulations do not specify exactly what 'effective controls and procedures' a pharmacy must use to prevent diversion of controlled substances."
- But pharmacies "may not remain deliberately ignorant or willfully blind of the prescription information it has"

In re National Prescription Opiate Litig., 2020 WL 5642173 (N.D. Ohio Sept. 22, 2020)

Case Horizon

Case Horizon

- Track One 1B
  - Trial postponed indefinitely
- Track Two (Remanded to S.D.W.Va.)
  - Cabell County, W.Va. & City of Huntington, W.Va.
  - Trial rescheduled to January 2021
- Trial Three
  - Trial scheduled for May 2021
- Subsequent Tracks

Questions?

Enforcement and Compliance Risks Associated with the Opioid Crisis: Who's to Blame will Cast a Wide Net

Robert G. Trusiak, Esq.

Health Care Compliance Association
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Robert Trusiak

- Robert Trusiak represents hospital and physician clients on regulatory, statutory, and enforcement issues. He separately provides complete health care consulting services for physician providers, hospitals, research labs, skilled nursing facilities, pharmaceutical companies, and durable medical equipment entities and counsels clients on a number of state and federal health care regulatory matters, including HIPAA, HITECH, Shield Act, health care reform, fraud and abuse, Stark Law and health care compliance issues.

- Previously, Robert served as Chief Compliance Officer, Senior Associate General Counsel and Privacy Officer at Kaleida Health where he successfully managed the internal Compliance team, litigation teams of outside counsel, litigated administrative and contractual actions, ensured regulatory and statutory compliance, and resolved matters involving accrediting and enforcement entities as well as individual matters.

- Robert also served as Assistant United States Attorney until his retirement in 2012 as Chief of the Affirmative Civil Enforcement Unit. Robert prosecuted civil and criminal cases on behalf of the United States of America involving health care fraud, Department of Defense fraud, HUD fraud, grant fraud, VA fraud, ERISA violations, Tax fraud, Securities fraud, Customs violations, USDA violations, and all forms of procurement fraud.

- Robert was also an Adjunct Professor, University at Buffalo, SUNY, teaching in 2015 and 2016 a graduate level course entitled Health Care Fraud and Abuse.

HOW TO MANAGE THE OPIOID COMPLIANCE CRISIS

- The Wide Net
- Stay Informed
- Compliance
- Policies
- Monitoring
- Governance
- Know the law

Who's to blame will cast a wide net

- The management of opioid risk from a compliance program perspective must account for the broad nature of the risk.
- The MDL litigation is merely an outgrowth of opioid risk on the manufacturer and distributor level.
  - The federal multidistrict litigation consolidated in Ohio contains roughly 3,000 cases filed by cities and counties, as well as Native American tribes, that want money for health care and law enforcement costs related to the opioid epidemic. The suits accuse the opioid manufacturers, distributors and pharmacy chains of feeding the epidemic by downplaying the risks of addiction and failing to monitor suspicious orders.
- Natalie's presentation provided a thoughtful assessment of the MDL
- MDL may seem far away as a compliance risk to a compliance officer at an institutional provider or physician practice.
- MDL risk is only one of many opioid impactful efforts.

Who's to blame will cast a wide net

- There are other areas of opioid risk similar and distinct from the MDL litigation. Do not view the MDL litigation as the totality of opioid enforcement risk with its limitations of defendants to manufacturers and distributors.
- Institutional providers, payers, physician practices, physicians, hospital pharmacies surely have a much more limited opioid risk profile.
- The more limited risk profile, however, still creates real risk requiring real compliance efforts.
- The proceeding discussion will address some aspects of non MDL opioid risk from a **regulatory and institutional provider perspective** hopefully serving to inform compliance officer 2021 work plan efforts.

Regulatory Example: BETH ISRAEL MEDICAL CENTER

- Beth Israel Medical Ctr (BIMC) operated a hospital and health care center that operated an opioid treatment program (OTP).
- The New York State Office of Medicaid Inspector General conducted an audit in 2018 that addressed OTP claim submissions for 2014-2016. See https://www.health.ny.gov/health_care/medicaid/decisions/docs/beth_israel_medical_center_04-24-2020.pdf, p.2.
- BIMC successfully proceeded through OASAS and Joint Commission audits in 2018. *Id.*, p. 26.
- The OMIG audit identified 11 disallowed claims totaling $407.90. *Id.*, p. 27.

Regulatory Example: BETH ISRAEL MEDICAL CENTER, cont'd

- 4 of the 5 audit categories involved only one finding per category. *Id.*, p. 30.
- OMIG never claimed the findings of inadequate documentation affected the patient care of one person.
- The below comments by the ALJ require no elaboration:
  - The Appellant claims that the OMIG's recovery of the overpayment using extrapolation methodology will result in the closure of one clinic serving anywhere from 400 to 1500 patients. That business decision is irrelevant to this review of a documentation audit and a resulting Medicaid overpayment. *Id.*, p. 31.

Regulatory Example: BETH ISRAEL MEDICAL CENTER, cont'd

- The Appellant also contended that it is unjust, amidst a growing opioid epidemic, to impose an overpayment of $7,745,764 upon a large OTP that serves disenfranchised members of the general population. It is New York State policy to [ensure] …OTP patients received care in accordance with all legal requirements. *Id*., p. 30.
- The ALJ rejected BIMC evidence that record storage inefficiencies resulted in some misplaced paperwork despite the provider's expenditure of more than $300,000 to upgrade record keeping. "The Appellant, however, had an ongoing and independent obligation to correct any inadequate compliance with documentation requirements. Making the changes did not account for or excuse the failure to produce the documents which the Appellant was required to provide for this audit." Id., p. 26.
  - What was the equitable value of this expenditure?
- The ALJ also rejected subsequently discovered documentary evidence bearing on certain audit findings. *Id*., p. 14. The ALJ also rejected circumstantial evidence supporting compliance with record requirements. *Id*., p. 15.
  - Pls note the Director of Pharmacy at BIMC in 2014 was charged with stealing approximately 200,000 oxycodone tablets with an approximate street value of $5.6 million.

Stay Informed

- Stay informed about what is happening on the regulatory, legislative, enforcement and judicial fronts regarding opioid enforcement.
- Collaborate with internal departments, patient advocacy groups, clinical experts and others to develop strategies to handle risk areas related to opioid fraud and abuse.

STAYING INFORMED: AN EXAMPLE-- "SOBER HOMES"

- The Department of Justice (DOJ) announced in October a joint investigation involving the HHS OIG, FBI, and DEA which resulted in a historic nationwide enforcement action involving 345 charged defendants across 51 federal districts, including more than 100 doctors, nurses and other licensed medical professionals, who submitted more than $6 billion in false and fraudulent claims to federal health care programs and private insurers.

SOBER HOMES

- An aspect of this takedown involved illegal prescription and/or distribution of opioids and other frauds involving more than 240 defendants allegedly participating in schemes to submit more than $800 million in false and fraudulent claims to Medicare, Medicaid, TRICARE, and private insurance companies for treatments that were medically unnecessary and often never provided.
- Also included were charges against medical professionals and others involved in the distribution of more than 30 million doses of opioids and other prescription narcotics

STAY INFORMED: THE BIDEN OPIOID POLICY—WHAT DOES THAT MEAN FOR YOU?

- Under the Trump administration, the DOJ's focus has only been on a relatively small number of participants in the DEA's registry. Conversely, Biden's policy tells government investigators to make sure companies are complying with regulations for monitoring and reporting suspicious orders of opioids.
- **The next wave of enforcement actions is going to be who else is there beside the primary manufacturers, distributors and pharmacy chains.**

See https://www.law360.com/health/articles/1323869/biden-opioid-plan-puts-pharmacies-on-notice?nl_pk=d500baca-eda4-41c0-acc2-23589e7a118d&utm_source=newsletter&utm_medium=email&utm_campaign=health?copied=1.

COMPLIANCE
THE OLD STAND BY: DIVERSION

- There are certain compliance areas in an institutional provider setting that always remain compliance relevant: upcoding, physician compensation, 340B, med necessity of inpatient stays, lease arrangements, HIPAA compliance, kickback compliant vendor relationships AND…..
- DIVERSION.

DIVERSION

- **Drug diversion not detected is not the same as drug diversion not occurring.**
- Drug diversion is a multifactorial and multidisciplinary issue, particularly involving pharmacy, nursing and medical staff. Organizations struggle with diversion prevention and often over-rely on automation to control access and detect diversion activity. See, *e.g.*, I STOP, https://www.health.ny.gov/professionals/narcotic/prescription_monitoring/.
- An area of drug diversion that hospital pharmacies tend to overlook is assessment of diversion safeguards and the segregation of the buyer and receiving duties.
  - See the following article for a comprehensive assessment of institutional diversion risks: https://www.journalofhospitalmedicine.com/jhospmed/article/202732/hospital-medicine/diversion-controlled-drugs-hospitals-scoping-review.

REMEDIAL EFFORTS ADDRESSING THE PRECEDING ENFORCEMENT AND DIVERSION MATTERS— do it and document it

- Training
  - Pharmacy staff should receive regular and timely updates on expected behavior for controlled drug handling so they are aware if something out of the norm is happening.
  - The hospital has a zero tolerance of sexual harassment and wrongful HIPAA disclosures.
    - Train all workforce members about diversion and prevention and instill a zero-tolerance culture against diversion.
- Promotion of hotline and whistleblower compliance
  - Do you promote diversion avoidance in the same way as fraud and abuse?

REMEDIAL EFFORTS CONT'D

- **Segregation of Duties or Checks and Balances**
  - Does your hospital pharmacy combine the roles of buyer and receiver?
    - Does your Finance Department permit the same person to receive the vendor invoice and pay the same invoice?
      - Probably not to avoid fake vendor schemes.
  - Many pharmacies utilize a pharmacist to receive and check scheduled drugs against the manifests and then place them in their designated secure location. An extra set of eyes on what is being ordered and received makes another person aware of what is coming into the pharmacy. Hospital pharmacies sometimes fail to realize how easy it is for a buyer to order something without their knowledge and then divert the product during the receiving process without appropriate check and balances.
    - See https://www.beckershospitalreview.com/hospital-management-administration/drug-diversion-in-hospitals-are-you-next.html.

REMEDIAL EFFORTS CONT'D

- Audits.
  - Effective compliance requires a robust and not rote audit component.
  - The above DOJ takedown involving opioids and other controlled substances involved medically and ghost patients.
  - Does your compliance plan contain even a modicum of effort designed to identify medically necessary scripts, including opioids, as well as actual patients?
  - Payer Collaboration
    - Do you interface with payers, if necessary, to determine changes in prescribing habits?
  - Use the tripartite HITECH security assessment in the pharmacy

REMEDIAL EFFORTS: Policies

Update and monitor policies pertaining to physical medication safeguards, inventory management and risk identification.

REMEDIAL EFFORTS: Monitoring

- Coordinate with internal personnel to initiate internal data monitoring that specifically targets opioid fraud and abuse.
- Have an interdisciplinary team to review prescriber analysis and treatment protocols.
- Hospital pharmacists are uniquely qualified to curb opioid diversion. Establish an opioid diversion prevention and detection programs through which pharmacists can ensure the supply of opioids are used appropriately and prevent misuse through diversion.
- Pharmacists can also use data from the NYS Prescription Monitoring Program Registry to track prescribing practices and patient behaviors that can lead to abuse.

REMEDIAL EFFORTS: Governance

- Inform your governing boards, or board compliance committee, of an overview and updates on new opioid regulations and changes in the law.
- The board needs to appreciate how the opioid epidemic affects the organization as well as expectations from government agencies.

REMEDIAL EFFORTS: ***EFFECTIVE*** COMPLIANCE

- The "Principles of Federal Prosecution of Business Organizations" in the Justice Manual describe specific factors that prosecutors should consider in conducting an investigation of a corporation, determining whether to bring charges, and negotiating plea or other agreements.
- These factors include "the adequacy and effectiveness of the corporation's compliance program at the time of the offense, as well as at the time of a charging decision" and the corporation's remedial efforts "to implement an adequate and effective corporate compliance program or to improve an existing one."

Evaluating a Corporate Compliance Program Regarding Opioid Abuse

- In the June 2020 U.S. Department of Justice updated guidance document on *Evaluation of Corporate Compliance Programs*, three "fundamental questions" a prosecutor should ask are identified:
  1. "Is the corporation's compliance program well designed?"
  2. "Is the program being applied earnestly and in good faith?" In other words, is the program adequately resourced and empowered to function effectively?"
  3. "Does the corporation's compliance program work in practice?"
- A health system can take several steps to establish or enhance its compliance program to mitigate opioid abuse.

Evaluating a Corporate Compliance Program--Continued

- DOJ GUIDELINES FOR TAKING DISCLOSURE, COOPERATION, AND REMEDIATION INTO ACCOUNT IN FALSE CLAIMS ACT MATTERS, May 7, 2019.
  - These DOJ Guidelines are also helpful in assessing the effectiveness of compliance guidance, in general, or targeted to mitigate opioid risk. See https://www.justice.gov/jm/jm-4-4000-commercial-litigation.

Evaluating a Corporate Compliance Program--Continued

- **The Basics**
  - Cooperation does not include disclosure of information required by law.
  - Cooperation also does not include the disclosure of information that is under an imminent threat of discovery or investigation.
  - The Department will not award any credit to an entity or individual that conceals involvement in the misconduct
  - Entities and individuals are entitled to assert their legal rights and, unless required by law, do not have to cooperate with a government investigation.
  - Eligibility for credit for voluntary disclosure or other forms of cooperation is not predicated on waiver of the attorney client privilege.

Evaluating a Corporate Compliance Program--Continued

- **Remedial Measures**
  - Demonstrate a thorough analysis of the cause of the underlying conduct and, where appropriate,
  - remediation to address the root cause;
  - Implement or improve an effective compliance program designed to ensure the misconduct or similar problem does not occur again;
  - Appropriately disciplining or replacing those identified by the entity as responsible for the misconduct either through direct participation or failure in oversight, as well as those with supervisory authority over the area where the misconduct occurred; and
  - Any additional steps demonstrating recognition of the seriousness of the entity's misconduct, acceptance of responsibility for it, and the implementation of measures to reduce the risk of repetition of such misconduct, including measures to identify future risks.

Program Enhancement (cont.)

- Regularly audit opioid dispensing mechanisms and storage facilities and immediately address the audit findings.
  - Determine why dosage/unit counts are off and how the controlled substances went missing.
  - Test vials/ampules of liquid opioids to see whether they have been surreptitiously replaced with saline or water.
- Consider the placement of opioid dispensers/machines. Diverters easily take advantage of machines placed in isolated rooms, out of public view, or near bathrooms where the diverter can quickly hide after stealing the medication.
- Consider installing security cameras near the dispensers.

The Evolution of the Opioid Crisis: Where, When and How Does It End?

- Crystal balls are at a premium in the risk management business.
- None of us know the end point of the opioid crisis.
- We all need to address the opioid risks consistent with our resources.
- The fact we cannot do everything does not mean we should do nothing.

Questions?

Robert G. Trusiak, Esq.
300 International Drive, Suite 100
Williamsville, NY 14221
(716)352-0196
robert@trusiaklaw.com
www.trusiaklaw.com